CASE CV0244

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John M. Kilcoyne	John M. Kilcoyne	February 4, 2005
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
Michael J. Waring et al.
APPLICATION NO: 09/341,821
FILED: September 1, 1999
FOR: MULTI-DOSE WOUND GEL

Art Unit: 1615
Examiner: Isis A.D. Ghali

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APPEAL BRIEF

Sir:

This is an appeal from the Final Rejection of claims 1-6, 8-10, 13-15 and 17-20.

(1) REAL PARTY IN INTEREST

The real party in interest in this appeal is Bristol-Myers Squibb Company, a Delaware corporation, having a place of business at 345 Park Avenue, New York, NY 10154.

(2) RELATED APPEALS AND INTERFERENCES

The undersigned knows of no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) STATUS OF CLAIMS

Claims 1-6, 8-10, 13-15 and 17-20 are pending in this application.

Claims 1-4, 13 and 17 stand rejected under 35 USC §102(b) as being anticipated by US Patent No. 3976223 ("Jass et al."); claims 5, 6, 10, 14, 15 and 18 stand rejected under 35 USC §103 as being unpatentable over Jass et al. in view of EP 666 081 ('081); and claims 8, 9, 19 and 20 stand rejected under 35 USC §103 as being unpatentable over US Patent No. 5059187 ("Sperry et al.") in view of Jass et al.

Appendix A annexed hereto contains a copy of the claims involved in the appeal. The appealed claims are claims 1-6, 8-10, 13-15 and 17-20.

(4) STATUS OF AMENDMENTS

Appellants appeal the decision dated June 30, 2004, of the Primary Examiner finally rejecting claims 1-6, 8-10, 13-15 and 17-20. An Amendment After Final Rejection has been entered, but no claims were allowed. Accordingly, claims 1-6, 8-10, 13-15 and 17-20 remain pending in this application.

(5) SUMMARY OF INVENTION

The present invention relates to a self-sealing barrier aerosol vessel containing multiple doses of a wound gel, a method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, a multiple dose, sterile wound gel contained within a self-sealing barrier aerosol vessel, a method of treating wounds with a wound gel from a self-sealing barrier aerosol vessel containing multiple doses of a wound gel and a method for dispensing multiple doses of a wound gel from a single dispenser.

(6) ISSUES

The issues on appeal are whether claims 1-4, 13 and 17 are anticipated under 35 USC §102(b) by US Patent No. 3976223 ("Jass et al."); whether claims 5, 6, 10, 14, 15 and 18 are patentable under 35 USC §103 over Jass et al. in view of EP 666 081 ('081); and whether claims 8, 9, 19 and 20 are patentable under 35 USC §103 over US Patent No. 5059187 ("Sperry et al.") in view of Jass et al.

(7) GROUPING OF CLAIMS

Appellants submit that each of the rejected claims is separately patentable. For purposes of this appeal, however, appellant understands that claims 1-4, 13 and 17 will stand or fall together; that claims 5, 6, 10, 14, 15 and 18 will stand or fall together; and that claims 8, 9, 19 and 20 will stand or fall together.

(8) ARGUMENTS

I. Claims 1-4, 13 and 17 are not anticipated under 35 USC §102(b) over US Patent No. 3976223 ("Jass et al.")

According to the rejection, Jass et al. disclose an aerosol container containing a gel; the aerosol is provided by mechanical stream break up features and, according to the rejection, is therefore self-sealing; and the aerosol is not a single dose container as *implied* (emphasis added) by the effort made to avoid contamination of the contents during use.

However, the purpose of the package of Jass et al. is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. According to Jass et al., only the lower chamber of the outer container is pressurized with a gas through a self-sealing plug in the container bottom. See, *e.g.*, column 2, lines 53-57. With respect to some implication read into Jass et al., appellants submit that Jass et al. does not address the avoidance of contamination during use. Rather, the avoidance of contamination appears to be with respect to storage. See, *e.g.*, column 5, lines 23-32 and column 6, lines 8-13.

In response to these arguments, the rejection asserts that the aerosol container in Jass et al. is self-sealing, citing col.4, line 27; that avoidance of contamination during use is not recited in the rejected claims; and that the feature where only the lower part is pressurized is not recited in the rejected claims. However, col. 4, line 27, again relates only to the lower chamber of the outer container of Jass et al. Consequently, the container in Jass et al. is not self-sealing as required in the rejected claims. Moreover, that the feature regarding the lower part is pressurized is not in the rejected claims is correct. That is not a requirement of the instant invention, but rather it is a distinguishing feature required of the container in Jass et al.

For at least these reasons, appellants submit that the basis for the rejection is without merit. Accordingly, appellants request that this rejection be reversed.

II. Claims 5, 6, 10, 14, 15 and 18 are patentable under 35 USC §103 over Jass et al. in view of EP 666 081 ('081)

Appellants submit that there appears to be a basic misunderstanding of the invention. The invention is not simply substituting one *liquid* in any aerosol device for another. The focus of the invention in Jass et al. is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. Since that is the focus of the invention, there is no reason other than hindsight to substitute the composition of the '081 document for the composition of Jass et al.

Further, while the composition in the '081 document is a gel, the '081 document does not provide that which is missing in Jass et al. as noted above.

Moreover, the rejection indicates that the features upon which appellants rely (*i.e.*, storage of a plurality of flowable substances in a single package) are not recited in the rejected claim(s). That is correct. This feature is not a requirement of the instant invention, but rather it is a distinguishing feature required of the container in Jass et al.

For at least these reasons, appellants submit that the claimed invention is patentable over the cited art, and they request that this rejection be reversed.

III. Claims 8, 9, 19 and 20 are patentable under 35 USC §103 over US Patent No. 5059187 ("Sperry et al.") in view of Jass et al.

Essentially, according to the rejection, Sperry et al. teach an aerosol container and a method for cleaning the wound as claimed in the instant application. Appellants strenuously disagree. In fact, Sperry et al. teach away from the present invention in at least two important ways. First, Sperry et al. do not teach or suggest a dispensing vehicle that contains multiple doses of wound-treating material. Instead, Sperry et al. teach away from a multiple dose container stating that "the container and method ... [is such that] the container contains enough wound cleaning solution to irrigate the average wound or abrasion." (See col. 1, lines 52-56.) Thus, although the contents of the container in Sperry et al. can be sterilized, Sperry et al. do not disclose a dispensing device that can contain more than a single dose of wound-treating material. Thus, nothing in Sperry et al. suggests a wound gel dispenser capable of dispensing multiple doses while keeping the wound gel contents reasonably free of contaminants.

The rejection notes that the feature upon which appellants rely (*i.e.*, aerosol containing multiple doses) is not recited in the rejected claims. The feature was recited in claim 19 (through its

dependency) and claim 20. It has been added to claims 8 and 9 by the amendment after final rejection which has been entered.

A second way in which Sperry et al. teach away from the present invention is in the fact that Sperry et al. disclose a method of dispensing liquid, not gel, to a wound. This method lacks the complicating factors of dispensing a gel that is in gel-form within the container.

Further, Sperry et al. do not make up for the deficiencies of Jass et al. as noted above. For at least these reasons, appellants request that this rejection be reversed.

IV. Conclusion

For all the reasons set forth herein, it is urged that the rejections of claims 1-6, 8-10, 13-15 and 17-20 should be reversed. Allowance of this application with claims 1-6, 8-10, 13-15 and 17-20 is in order. Such action is earnestly solicited.

Respectfully submitted,

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APPENDIX

1. A self-sealing barrier aerosol vessel containing multiple doses of a wound gel for the treatment of wounds.

2. A vessel as claimed in claim 1 wherein the gel comprises a hydrocolloid.

3. A vessel as claimed in claim 1 wherein the gel comprises a natural gelling agent.

4. A vessel as claimed in claim 1 wherein the gel comprises a glycol.

5. A vessel as claimed in claim 1 wherein the gel comprises:

(a) from about 0.05% to 10% by weight of a natural gelling agent;

(b) from about 1.0% to 10% by weight of a hydrocolloid;

(c) from about 5.0% to 30.0% by weight of an alkylene glycol; and

(d) at least 50% by weight of water.

6. A vessel as claimed in claim 1 wherein the gel is sterile.

8. A method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, the method comprising the steps of:

(i) filling an inner container with gel, said inner container being contained within an outer casing container;

(ii) sealing the inner container with an opening valve; and

(iii) introducing a pressure medium between the inner container and the outer casing container.

9. A method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, the method comprising the steps of :

(i) filling an inner container with non-sterile gel, said inner container being contained within an outer casing container;

(ii) sealing the inner container with an opening valve;

(iii) sterilizing the vessel and gel contained within it; and

(iv) introducing a pressure medium between the inner container and the outer casing container.

10. A multiple dose, sterile wound gel contained within a self-sealing barrier aerosol vessel.

13. A method for treatment of a wound comprising discharging onto the wound a wound gel from a self-sealing barrier aerosol vessel containing multiple doses of a wound gel.

14. A method for the treatment of a sinus wound comprising discharging into a sinus cavity a wound gel from a self-sealing barrier aerosol vessel containing multiple doses of a wound gel.

15. The method of claim 13 wherein said wound gel is sterile.

17. The method of claim 13 wherein said gel is a hydrocolloid-containing gel.

18. The method of claim 13 wherein said gel has a viscosity of between 150 and 800 Pas.

19. The method of claim 13 wherein said gel-containing vessel is prepared by the following steps:

(i) filling an inner container of said vessel with a non-sterile gel;

(ii) sealing the inner container with an opening valve;

(iii) sterilizing said vessel and gel; and

(iv) introducing a pressure medium between the inner container and the outer casing container.

20. A method for dispensing multiple doses of a preservative-free therapeutic gel from a single dispenser to a wound in need of such gel comprising the steps of:

(a) providing a self-sealing barrier aerosol dispenser with said gel therein by

(i) preparing said self-sealing barrier aerosol dispenser to comprise an inner container and an outer casing container;

(ii) filling said inner container with said gel;

(iii) sealing said inner container with an openable and closeable dispensing valve;

(iv) sterilizing the container and gel therein; and

(v) introducing a pressure medium between said inner container and said outer

casing container; and

(b) opening and closing said dispensing valve to dispense two or more doses of said gel into said wound, whereby the risk of contamination of the gel remaining in said dispenser is substantially eliminated.